

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

FILED

JUL 1 2015

GILEAD SCIENCES, INC., and  
EMORY UNIVERSITY,

U.S. DISTRICT COURT-WVND  
CLARKSBURG, WV 26301

Plaintiffs,

v.

CIVIL ACTION NO. 1:14-cv-99

MYLAN INC. and  
MYLAN PHARMACEUTICALS INC.,

Defendants.

ORDER/OPINION

This case is before the Court pursuant to Plaintiffs Gilead Sciences, Inc. And Emory University's Motion to Compel Defendants to Produce Documents. (Docket No. 160.) Defendants, Mylan Inc. And Mylan Pharmaceuticals Inc., filed their Opposition to Plaintiffs' Motion to Compel Documents on June 22, 2015. (Docket No. 176.) Plaintiffs filed a Reply in Support of its Motion to Compel on June 26, 2015. (Docket No. 183.) This matter was referred to the undersigned by District Judge Irene M. Keeley on June 01, 2015. (Docket No. 161.) Oral arguments on the matter were heard by the undersigned on June 29, 2015. (Docket No. 180.)

I. Relevant Procedural History

On June 09, 2014, Plaintiffs filed a complaint in this Court alleging three counts of infringement on a patent. (Docket No. 1.) On June 27, 2014, Plaintiffs filed an amended complaint with no additional counts.<sup>1</sup> (Docket No. 14.) Defendant filed an answer to the amended complaint

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<sup>1</sup>A second amended complaint, filed on January 22, 2015, added a fourth count of infringement on a patent. (Docket No. 94.)

on August 08, 2014<sup>2</sup>. (Docket No. 24.) On October 06, 2014, Judge Keeley filed a scheduling order, requiring fact discovery to be completed by May 28, 2015. (Docket No. 53.)

Plaintiffs' first set of requests for production were served on Defendants on November 19, 2014. (Docket No. 72.) Defendants' objections and responses to the requests were served on Plaintiffs on December 22, 2014. (Docket No. 85.)

## **II. Analysis and Order**

The dispute arises from Plaintiffs' Motion to Compel Defendants to Produce Documents. (Docket No. 160.) As part of Plaintiffs' first set of requests for production, Plaintiffs requested documents pertaining to ANDA No. 90-049 (PEPFAR ANDA)<sup>3</sup>. (Docket No. 183.) In the Defendants' December 22, 2014 responses, Defendants objected to the request. (Docket No. 176.) Defendants now contend that the motion to compel is untimely, because the Northern District of West Virginia Rules of Civil Procedure prescribe a 30 day time limit to compel discovery upon an objection. (Docket No. 176); N.D. W. Va. L.R. Civ. P. 37.02(b). Plaintiffs contend that they are entitled to discovery of the documents related to PEPFAR ANDA as a means to test it, in order to address the Defendants' invalidity defense, which Plaintiff contends was raised well after the initial 30 day time limit had expired. (Docket No. 183.)

### **A. Invalidity Defense**

An invalidity defense is one in which the validity of the patent is challenged under the

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<sup>2</sup> Defendant filed an answer to the second amended complaint on February 09, 2015. (Docket No. 97.)

<sup>3</sup> It should be noted that the PEPFAR ANDA is not the product in dispute: Plaintiffs allege that Defendants' ANDA No. 20-6436 infringes upon Plaintiffs' Truvada patent. (Docket No. 176.)

doctrines of anticipation, obviousness, or enablement. Dey, L.P. v. Teva Parenteral Medicines, Inc., 6 F. Supp. 3d 651, 663 (N.D.W. Va. 2014). Enablement theory is a method of challenging a patent's validity by claiming that a patent has failed to meet the enablement requirement of 35 U.S.C. § 112. See Generally L.P. v. Teva Parenteral Medicines, Inc., 6 F. Supp. 3d 651, 664 (N.D.W. Va. 2014). The statute mandates that a valid patent must "contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains." 35 U.S.C. § 112. This is the enablement requirement. Id. In the case at bar, by raising an invalidity defense based in enablement theory, the Defendants presumably seek to challenge the validity of the Plaintiffs' Truvada patent, as a defense to the alleged infringement, by claiming that the original patent application did not satisfy the enablement requirement. Plaintiffs assert that because the Defendants raised an invalidity defenses based upon enablement theory the Plaintiffs should be entitled to discovery on the PEPFAR ANDA in order to defend against the invalidity claim.

However, an invalidity defense looks no further than the four corners of initial patent and patent application. Streck, Inc. v. Research & Diagnostic Sys., Inc., 665 F.3d 1269, 1285 (Fed. Cir. 2012). As the Supreme Court has explained, "the ultimate question of patent validity is one of law" designed to determine whether the patent application meets all of the requirements of patentability. Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238, 2243 (2011). The analysis requires "an objective inquiry into the four corners of the [patent] from the perspective of a person of ordinary skill in the art." Streck, 665 F.3d at 1285 (quoting Ariad Pharm, Inc. V. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010)). When dealing with enablement theory specifically, the analysis should seek to determine whether the four corners of the patent-in-suit contain sufficient information to satisfy the

enablement requirements of 35 U.S.C. § 112, from the perspective of “a person of ordinary skill in the art.” Id.

Plaintiffs assert that they require documents related to the PEPFAR ANDA to defend against such a claim of invalidity. (Docket No. 183.) This argument fails because everything that the Plaintiffs would need to defend against a claim of invalidity through enablement theory is within the four corners of the Plaintiffs’ own patent. Streck, 665 F.3d at 1285. As such, the Court finds no reason to forego the requirements of the Local Rules of Civil Procedure in order to provide Plaintiffs with documents that they do not even need to defend against such a claim.

### **B. 30 Day Time Limit**

The Local Rules of Civil Procedure prescribe that upon objection to an interrogatory or request for production, the moving party has 30 days to file a motion to compel or a similar motion in aid of discovery. N.D. W. Va. L.R. Civ. P. 37.02(b). In lieu of such a motion, the right to compel is waived. Id. The Court may grant exceptions to this rule, if the failure to file was caused by excusable neglect or by some action of the non-moving party. Id.

Here, the Court finds no such reason to grant an exception. Even if the Court were to accept that these documents are vital to establishing Plaintiffs’ defense to the enablement theory, it must be noted that invalidity as a defense first appeared in the Answer, Defenses, and Counterclaims of Mylan Pharmaceuticals Inc. and Mylan Inc., filed on August 12, 2014. (Docket No. 24.) This defense was raised long before the requests for production (served on November 19, 2014) and subsequent objections became an issue. (Docket No. 72.) As such, the Court is not persuaded by the Plaintiffs’ claim that they were unaware of this defense prior to the expiration of the 30 day time limit.

The Plaintiffs should have been aware of the invalidity defense as early as August 12, 2014.

If the Plaintiffs believe that documents related to the PEPFAR ANDA are so crucial to defending against a claim of invalidity, the Plaintiffs could and should have contested the objection within the 30 day time period. Plaintiffs failed to do so, instead waiting 158 days to file the motion to compel. The Court finds no excusable neglect or action from the non-moving party that caused such a delay. As such, the motion is untimely and the Plaintiffs have waived the right to file a motion to compel.

Accordingly, Plaintiffs' Motion to Compel Defendants to Produce Documents (Docket No. 160) is **DENIED**.

It is so **ORDERED**.

The Clerk of the Court is directed to provide a copy of this Order/Opinion to counsel of record and to remove Docket No. 160 from the list of motions actively pending before this Court.

DATED: July / , 2015

  
JOHN S. KAULL  
UNITED STATES MAGISTRATE JUDGE